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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,414	09/18/2001	Nancy L. Parenteau	56001/02021	1042

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KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.

09/955,414

Applicant(s)

PARENTEAU ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 7-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 7-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoval (WO 99/04720) in view of Murphy et al (WO 00/29553). Stoval discloses a method of forming an opening in an annular fibrosis (see page 10, line 1 to page 11, line 12 and Figure 2), removing at least a portion of the nucleus pulposis (see supra), and grafting a cultured connective tissue construct to close the opening (see page 2, lines 10-18, page 3, lines 7-14, and page 4, lines 10-15). The layer of extracellular matrix as claimed is met by the layer of extracellular matrix material that is inherently present around the cultured cells of Stoval.

However, Stoval fails to clearly disclose using a bioremodelable construct in the method as claimed. Murphy teaches that it was known to make bioremodelable graft constructs without exogenous matrix components or synthetic members in the repair a variety of tissues; see pages 1-19 and claim 19 thereof and see the present specification and the paragraph bridging pages 5 and 6. Particularly, Murphy teaches the use of bioremodelable constructs as replacements or improvements over those constructs of the art that relied upon mesh supports; see page 10, lines 21-29. Murphy also discloses that any tissue type can be used to replace the corresponding tissue; see page 19, lines 7-17. In this way, Murphy provides a nexus from prior art constructs of

Art Unit: 3738

Stoval to the use of the constructs disclosed therein that do not have exogenous support materials or synthetic materials. Therefore, it is the Examiner's position that it would have been obvious to use the bioremodelable construct of Murphy as the graft implant material of Stoval for the same reasons that Murphy teaches using the same.

With regard to the paragraph bridging pages 5 and 6 of the present specification, it is noted that MPEP 715 states:

"Where applicant has clearly admitted on the record that subject matter relied on in the reference is prior art. In this case, that subject matter may be used as a basis for rejecting his or her claims and may not be overcome by an affidavit or declaration under 37 CFR 1.131. In re Hellsund, 474 F.2d 1307, 177 USPQ 170 (CCPA 1973); In re Garfinkel, 437 F.2d 1000, 168 USPQ 659 (CCPA 1971); In re Blout, 333 F.2d 928, 142 USPQ 173 (CCPA 1964); In re Lopresti, 333 F.2d 932, 142 USPQ 177 (CCPA 1964)"

Regarding claim 3, since extracellular matrix is made of collagen, the same is present in the constructs of Stoval or Murphy.

Response to Arguments

Applicants' arguments filed February 26, 2007 have been fully considered but they are not persuasive.

The Applicants argue that the "underlined grafting/closing limitation has nothing to do with the tissue construct, the limitation of which is in the italics"; see page 3, lines 2-3 of the response. However, the Examiner disagrees and asserts that the grafting step particularly grafts the tissue construct to close the opening and that that tissue construct is further defined in the last five lines of the claim. The Applicants seem to be trying to artificially separate the parts of the claims as if they are unrelated. For this reason, the argument is considered to be wholly unpersuasive.

Applicants again argue that there is no motivation to combine Stoval and Murphy. However, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Applicants assert that the bulk material of Murphy could not be injected because it would "obstruct the injection device." However, Applicants assume that the injection device has a particularly small opening or port. The Examiner asserts that it is within the skill level of the ordinary artisan to inject bulk materials by selecting an appropriate injection device capable of performing the function. Alternatively, it would have been obvious to insert the Stoval device, as modified by Murphy, by hand or with an instrument capable of inserting the device.

Applicants argue that there is no reasonable expectation for success because the Murphy device cannot be injected. However, the Examiner asserts that since the Stoval and Murphy devices are both from the same art, one would have a reasonable expectation of success. Furthermore, it is certainly within the skill level of an ordinary artisan to select an appropriate injection device.

Also, Applicants also seem to argue that the use of bioremodelable matrix, without exogenous materials or synthetic components, is somehow critical to the disclosed invention. However, upon review of the present specification (see the

Art Unit: 3738

paragraph bridging pages 5 and 6), it is clear that there is no criticality to the claimed embodiments and that it is just one or many options; see MPEP 716.02 and 715.03 I C that are incorporated herein by reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilo
Primary Examiner
Art Unit 3738